REMARKS

Claims 1-2 and 4-5 are pending.

Withdrawn Rejections

Applicants note that the Examiner has withdrawn the previous rejection asserting that the claims were anticipated by Lal et al. (WO 00/00610).

Anticipation

Claims 1-2 and 4-5 remain rejected under 35 U.S.C. 102(e) on the assertion that they are anticipated by Walker et al. (U.S. Patent No. 6,277,574). According to the Examiner, Walker et al. claims the polynucleotide which encodes the polypeptide of SEQ ID NO: 50 and provides utility for the claimed polypeptide. The Examiner asserts that the Declaration Under 37 C.F.R. §1.131 which was previously submitted to overcome this rejection is insufficient. According to the Examiner, *In re Wilkinson* 134 USPQ 171 (CCPA 1962) and *In re Moore*, 170 USPQ 260 (CCPA 1971) require that, if the cited reference discloses a utility, the Declaration must establish that utility was known prior to the filing date of the cited reference.

Applicants maintain that the Declaration under 37 C.F.R. §1.131 which was previously submitted is sufficient to overcome the Walker reference. In particular, as discussed below, Applicants maintain the Declaration meets the requirement under 37 C.F.R. §1.131 that Applicants demonstrate conception of the claimed invention prior to the effective date of the Walker reference. Accordingly, Applicants maintain that the rejection under 35 U.S.C. 102(e) based on the Walker reference should be withdrawn.

A. U.S. Provisional Application Serial No. 60/088740 is Sufficient to Establish the Utility of the Claimed Polypeptide

The Examiner maintains that Applicants were not in possession of the utility of the claimed invention prior to April 9, 1999, the effective date of the Walker reference. Applicants maintain that, in contrast to the Examiner's position, U.S. Provisional Application Serial No. 60/088740 filed June 10, 1998 provides sufficient utility for the claimed invention.

Applicants filed U.S. Provisional Application Serial No. 60/088740 on June 10, 1998. As previously noted, this application discloses the polypeptide of SEQ ID NO: 50 (PRO1069). The uses provided for the polypeptide included the preparation of antibodies which recognize the

PRO1069 polypeptide. (See U.S. Provisional Application Serial No. 60/088740 page 26, line 3-page 31, line 10 and Example 7). The specification also described the use of the antibodies in diagnostic assays. (See U.S. Provisional Application Serial No. 60/088740 page 31, lines 12-25).

Applicants maintain that the filing of U.S. Provisional Application Serial No. 60/088740 on June 10, 1998 is sufficient to demonstrate Applicants' conception and demonstration of utility prior to the April 9, 1999 effective date of the Walker reference. In particular, Applicants note that U.S. Provisional Application Serial No. 60/088740 discloses that the polypeptide of SEQ ID NO: 50 has homology to channel inhibitory factor and MAT-8, each of which is involved in ion conductance. Applicants note that the PTO has issued many patents based upon the homology of the claimed polypeptide to biologically relevant polypeptides. For example, Applicants note that U.S. Patent No. 7,247,608 issued January 30, 2007 relates to a polypeptide having homology to adenosine deaminase. Likewise, U.S. Patent No. 6,642,039, issued Nov. 4, 2003, relates to a polypeptide having homology to human agmatinase. In addition, U.S. Patent No. 6,342,584, issued January 29, 2002, relates to a polypeptide having homolgogy to human pelota. These patents are provided as representative examples of patents issued based on the homology of the claimed polypetides to biologically relevant polypeptides, but there are many other such patents issued by the PTO. For the Examiner's convenience, Applicants provide these patents as Exhibits A-C. While Applicants appreciate that each application must be examined on its own merits, Applicants maintain that the disclosure of the homology of the claimed polypeptides to channel inhibitory factor and MAT-8 is sufficient to provide utility to the claimed polypeptides.

B. 37 C.F.R. §1.131 Allows Applicants to Overcome a Reference by Demonstrating Conception Prior to the Effective Date of the Reference Followed by Diligence in Reducing the Invention to Practice

Even if the disclosure in U.S. Provisional Application Serial No. 60/088740 is insufficient to demonstrate utility, which Applicants do not concede, Applicants maintain that the filing of this application, along with the statements in the Declaration under 37 C.F.R. §1.131, are sufficient to permit Applicants to overcome the cited Walker reference. In particular, Applicants maintain that U.S. Provisional Application Serial No. 60/088740 and the statements in the Declaration under 37 C.F.R. §1.131 demonstrate conception of the claimed invention prior to the effective date of the Walker reference. In addition, Applicants maintain that 37 C.F.R. §1.131 does not require Applicants to demonstrate utility of the claimed invention prior to the

effective date of the Walker reference because the demonstration of utility is part of reduction to practice, not conception.

As noted in Applicants' previous responses, 37 C.F.R. §1.131 explicitly states that a Declaration under that section must "establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application." 37 C.F.R. §1.131, emphasis added. Thus, the statute explicitly permits the Applicant to overcome a cited reference without demonstrating reduction to practice prior to the effective date of the reference.

The fact that 37 C.F.R. §1.131 does not require reduction to practice prior to the effective date of the reference was further recognized in the Federal Circuit's decision in *In re Mulder and Wulms*, 219 USPQ 189 (Fed. Cir. 1983). In that decision, the applicants had sent a draft patent application to a U.S. patent attorney prior to the effective date of the cited reference but had not filed a patent application until after the effective date of the reference. The court stated:

> As appellants have shown no actual reduction to practice of the invention in this country and no constructive reduction to practice in this country prior to the date of Rodgers, what Rule 131(b) says they have to show is conception in this country prior to Rodgers' date coupled with "due diligence from said date to *** the filing of the application." *In re Mulder and Wulms*, 219 USPQ 189, 192 (Fed. Cir. 1983).

Likewise, the M.P.E.P. also specifies that 37 C.F.R. §1.131 does not require reduction to practice prior to the effective date of the reference. In particular, M.P.E.P. § 715.07 states "The affidavit or declaration must state FACTS and produce such documentary evidence and exhibits in support thereof as are available to show conception and completion of the invention in this country ... **at least conception being at a date prior to the effective date of the reference**." M.P.E.P. § 715.07 also states that the showing of facts must be sufficient to show "**conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to a subsequent (actual) reduction to practice.**" *See id.* In view of the foregoing, it is clear that 37 C.F.R. §1.131 only requires Applicants to demonstrate conception prior the effective date of the Walker reference.

Applicants maintain that the filing of U.S. Provisional Application Serial No. 60/088740 and the statements in the Declaration under 37 C.F.R. §1.131 establish conception of the claimed invention prior to the April 9, 1999 effective date of the Walker reference. In particular,

Applicants maintain that the filing of U.S. Provisional Application Serial No. 60/088740 and the statements in the Declaration under 37 C.F.R. §1.131 establish that Applicants conceived of the sequence of the polypeptide of SEQ ID NO: 50 prior to the effective date of the Walker reference.

Applicants maintain that conception does not require a demonstration of utility and that, accordingly, Applicants have satisfied the requirements of 37 C.F.R. §1.131 even if the disclosure of U.S. Provisional Application Serial No. 60/088740 and the statements in the Declaration under 37 C.F.R. §1.131 are not sufficient to establish that Applicants determined the utility of the claimed polypeptide prior to the effective filing date of the Walker reference (which, as discussed above, Applicants do not concede). In the previous Response to Office Action submitted March 1, 2007, Applicants provided a discussion of the Federal Circuit's decisions in *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 32 USPQ2d 1915 (Fed. Cir. 1994) and *Oka v. Youssefyeh*, 7 USPQ2d 1171 (Fed. Cir. 1998), both of which found that determination of utility is part of reduction to practice rather than conception.

Applicants maintain that, since utility is part of reduction to practice rather than conception and since 37 C.F.R. §1.131 requires demonstration of conception prior to the effective date of the cited reference, U.S. Provisional Application Serial No. 60/088740 and the statements in the Declaration under 37 C.F.R. §1.131 are sufficient to overcome the Walker reference. Applicants note that the Examiner did not address *Burroughs Wellcome Co. v. Barr Laboratories, Inc.* and *Oka v. Youssefyeh* at all in the present Office Action. Likewise, the Examiner did not address Applicants position that utility is part of reduction to practice rather than conception in the present Office Action. Accordingly, Applicants respectfully request that the Examiner consider these points and specifically address them in the next communication.

For the foregoing reasons, Applicants maintain that they have satisfied all the requirements of 37 C.F.R. §1.131 and that, accordingly, the rejection based on the Walker reference should be withdrawn.

C. The Caselaw Cited by the Examiner is not Relevant to the Present Situation

The Examiner cites *In re Wilkinson*, 134 USPQ 171 (CCPA 1971) and *In re Moore*, 170 USPQ 260 (1971) for the proposition that, where the cited reference discloses a utility, 37 C.F.R. §1.131 requires Applicants to demonstrate that they determined the utility of the invention prior

to the effective date of the cited reference. Applicants maintain that *In re Wilkinson* and *In re Moore* are not relevant to the present situation.

As pointed out in the Amendment and Response to Office Action submitted March 1, 2007 in the present application, *In re Moore* related to a situation where the cited reference did not disclose utility for the claimed invention and the Applicants were able to swear behind the reference by demonstrating conception prior to the effective date of the reference. As previously noted, the statements in *In re Moore* suggesting that Applicants would have had to establish utility prior to the effective date of the reference if the reference had disclosed utility are dicta since the reference at issue in this decision did not disclose utility.

The facts in *In re Wilkinson* are similar to those in *In re Moore*. The cited reference in *In re Wilkinson* did not disclose a utility for the claimed compounds. Again, the statements in *In re Wilkinson* suggesting that Applicants would have had to establish utility prior to the effective date of the reference if the reference had disclosed utility are dicta since the reference at issue in this decision did not disclose utility.

For the foregoing reasons, Applicants respectfully request that the rejection under 35 U.S.C. §102(e) based on the Walker reference be withdrawn.

Conclusion

In view of the foregoing Applicants maintain that the application is in condition for allowance. Applicants invite the Examiner to call the undersigned if any remaining issues may be resolved by telephone.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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